

## **REMARKS / ARGUMENTS**

### ***Remaining Claims***

Seventeen (17) claims (Claims 1 – 8 and 10 – 18) remain pending in this application through this Amendment. Claims 9 and 19 – 20 have been deleted and Claims 1 and 18 have been amended herein. As explained in more detail below, Applicants have amended the claims to more clearly point out and distinctly claim the invention, and submit that all claims are now in condition for allowance and respectfully request such action. Attached hereto is a marked-up version of the changes made to the claims by the present amendment. The attached page is captioned "Version With Marking To Show Changes Made."

### ***Rejection of Claims 9 and 20 under 35 USC §112, second paragraph***

Claims 9 and 20 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 9 and 20 have been cancelled, thereby rendering this rejection moot. Applicants, therefore, respectfully request that this rejection be withdrawn.

### ***Rejection of Claims 1 - 8, 10 - 15, 18, and 19 under 35 USC §102(a) - Tsuzuki, et al.***

Claims 1 - 8, 10 - 15, 18, and 19 stand rejected under 35 USC §102(a) as anticipated by US Patent No. 6,121,327 to *Tsuzuki, et al.*

Applicants have amended independent Claims 1 and 18 to specify that the contact lens disinfection solutions of the present invention are substantially free of polyol compounds. This amendment finds support in the specification in Table 4, and throughout the written description as all disclosed solutions contain no polyol. Reading the present description, one of ordinary skill in the art that Applicants were in possession of the claimed invention; namely, a contact disinfection solution that provides markedly improved disinfection through the addition of BTP, despite the absence of a polyol compound in the solution.

In contrast, *Tsuzuki, et al.* are very clear that polyol compounds are a critical and required element of the solutions described therein. Specifically, Col.7, lines 13 – 18, teach that improved disinfection of the solution is due to "the combined use of the organic nitrogen disinfectant and the polyol." More specifically, lines 37 – 41 of Col. 7

teach that "if the amount of the polyol to be used is excessively small, the contact lens disinfecting solution does not exhibit a synergistically improved disinfecting effect."

While Examples 1 – 6 show a minor synergistic effect of the polyol in solutions buffered with BEC, Tsuzuki, et al provide no disinfection data for solutions buffered with bisTRIS propane (BTP) – all of which contain at least 1.5% polyol. In contrast, the present invention exhibits a major synergistic effect between PHMB and BTP in solutions not containing polyols (See Tables 1, 2, and 5).

Therefore, because *Tsuzuki, et al.* do not teach each and every of the claimed elements of the present invention, Claims 1 - 8, 10 - 15, 18, and 19 are not anticipated by this reference. Applicants, therefore, respectfully request that this rejection be withdrawn.

***Rejection of Claims 9, 16, 17, and 20 under 35 USC §103(a) - Tsuzuki, et al.***

Claims 9, 16, 17, and 20 stand rejected under 35 USC §103(a) as being obvious under US Patent No. 6,121,327 to *Tsuzuki, et al.* as applied above.

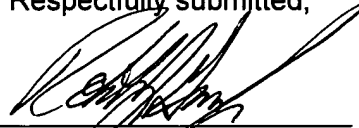
Claims 9 and 20 have been cancelled. Claims 16 and 17 are dependent, directly or indirectly, from Claim 1, discussed above. Applicants, therefore, respectfully request that this rejection be withdrawn.

**CONCLUSION**

In view of the foregoing and in conclusion, Applicants submit that the 35 USC §§102, 103, and 112 rejections set-forth in the Office Action have been overcome, and that the pending claims are not indefinite, anticipated by, or obvious over the cited art, either individually or in combination. Applicants request reconsideration and withdrawal of the rejection(s) set-forth in the Office Action. Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned.

Please address all correspondence to Novartis Corporation, Corporate Intellectual Property, One Health Plaza, Bldg. 430, East Hanover, NJ 07936-1080. The commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §1.16 and 1.17, or credit any overpayment, to Deposit Account No. 19-0134.

Respectfully submitted,



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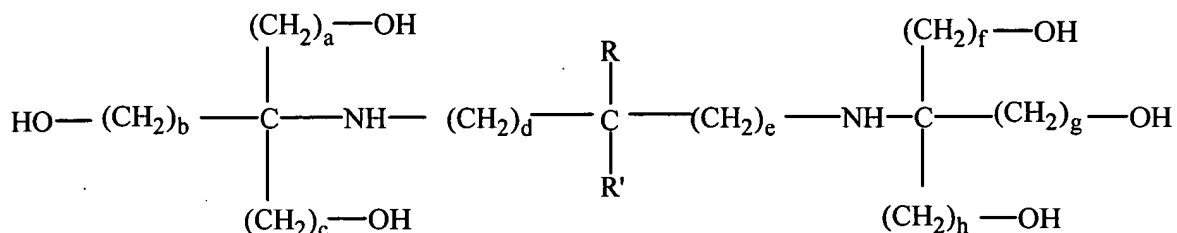
**VERSION WITH MARKING TO SHOW CHANGES MADE**

***In the Claims***

Please delete Claims 9 and 19 – 20.

Please amend Claims 1 and 18 as follows:

1. (amended) An aqueous solution for disinfecting a contact lens comprising a microbicide and a compound having the formula



wherein

a, b, c, d, e, f, g, and h are independently integers from 1 to 6; and

R and R' are independently chosen from the group consisting of —H, —CH<sub>3</sub>, —(CH<sub>2</sub>)<sub>2-6</sub>—H, and —(CH<sub>2</sub>)<sub>1-6</sub>—OH;

wherein said aqueous solution is substantially free of polyol compounds.

18. (amended) An aqueous solution for disinfecting a contact lens comprising from 0.1 to 10 ppm of a microbicide selected from the group consisting of polyhexamethylene biguanide and alexidine; and 0.001 to 0.2 mol/L of 1,3-bis(tris[hydroxylmethyl]methylamino)propane or a salt thereof, said solution adjusted to pH 6.8 to 7.5; wherein said aqueous solution is substantially free of polyol compounds.